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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,863	07/21/2003	Rogers C. Ritter	5236-000438	6412
28997	7590	07/05/2006	EXAMINER	
HARNESS, DICKEY, & PIERCE, P.L.C			EBRAHIM, NABILA G	
7700 BONHOMME, STE 400			ART UNIT	
ST. LOUIS, MO 63105			PAPER NUMBER	
			1618	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/623,863	<b>Applicant(s)</b> RITTER ET AL.	
	<b>Examiner</b> Nabila G. Ebrahim	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 36-39 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 36-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 25-34 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/4/04</u> .  | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

Receipt of the Information Disclosure Statement dated 3/4/04 is acknowledged.

### ***Election/Restrictions***

#### **Election/Restrictions**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24 and 36-39, drawn to an embolic material comprises magnetically responsive particles coated with a polymer, classified in class 424, subclass 78.08.

II. Claims 25-35, drawn to polymerizable embolic material comprising hydrophobic suspension of coated magnetically responsive particles, classified in class 525, subclass 11.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions can work independently, the design is different because the coating of group I is a polymer, while group II is a dispersion containing monomers. The modes of operation is different because group 1 can be ready for use while group II needs to be polymerized first.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Attorney Bryan K. Wheelock on 6/2/06 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-24, and 35-39. Affirmation of this election must be made by applicant in replying to this office action. Claim 25-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5, 8, and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ranney US 5213788 (Ranney).

Ranney discloses compositions and methods for selective access to tumor regions. This capability provides powerful contrast-enhancement agents for nuclear magnetic resonance imaging. A polyatomic complex, which includes intramolecular ferromagnetic coupling between metal atoms in the form of microspheres, which is associated with a polymer (abstract). Migration of particles and molecular aggregates (larger than 2 nm in diameter) can be accelerated by the application of appropriate surface coatings (col. 10, lines 49+). The preferred mean diameter falling between

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about 5 and 99 nanometers (col. 6, lines 44+), this ratio encompasses all ratios recited in claims 1-4. Ranney also discloses that iron oxide-dextran complex) achieves increased intramolecular paramagnetism (becomes superparamagnetic) and can be used in his invention (col. 11, lines 46+). Note that iron is a radio-opaque material.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1-24, 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ranney US 5213788 in view of Garibaldi et al. US 6364823 (Garibaldi), and further of view of Unger et al. US 6231834 (Unger).

Ranney has been discussed above. In addition, Ranney disclosed that the microspheres of his composition have cores (abstract)

Ranney is deficient in disclosing the kinds of iron oxides, the different polymer structures and the volume percentage of the magnetically responsive material.

Garibaldi discloses Embolic compositions for treating vascular defects such as aneurysms include a mixture of a biocompatible polymer material, a biocompatible solvent, and preferably also an adhesive Embolic compositions for treating vascular defects such as aneurysms include a mixture of a biocompatible polymer material, a biocompatible solvent, and preferably also an adhesive. The compositions preferably further comprise magnetic particles for controlling the delivery of the embolic agent. These magnetic particles preferably lose magnet strength over time, so that they do not interfere with subsequent magnetic diagnostic and therapeutic procedures. The compositions preferably also include radiopaque particles, which may be the magnetic particles, to facilitate imaging the embolic material (abstract). In the composition iron is used for both radiopacity and magnetic attraction (col. 4, lines 23+). Garibaldi included 40 weight percent magnetite (claim 16) and/or hematite (col. 12, lines 17+).

Garibaldi disclosed the use of long chain polymers. However neither Ranney nor Garibaldi disclosed the polymer backbone with the long chains of poly(propylene glycol) recited in the instant claims.

Unger teaches Improved methods for providing an image of an internal region of a patient. The composition disclosed by Unger includes a backbone polymer which is attached to a long chain polymer comprising polypropylene glycol (page 73 and page 39

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respectively). Unger's compositions are used in MRI (page 70) and as a diagnostic or therapeutic (embolic) agent (page 45).

It would have been obvious to one skilled in the art to use hematite or magnetite since both iron oxides are known in the art to have magnetic properties needed to control the embolic material inside the vessel.

Accordingly, it would have been obvious for one skilled in the art at the time the invention was made to combine the disclosure of Ranney with the knowledge of Garibaldi because Garibaldi disclosed that his invention provides improved methods and related devices for treating vascular defects, and it would also be beneficial to adjoin Unger since his invention includes different versions and multiple techniques for a therapeutic embolic agent beside the diagnostic techniques.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim

5/2/06



MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER